

Application No.: 10/623,193
Filing Date: July 18, 2003

REMARKS

In response to the Office Action mailed February 8, 2008, the Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following remarks.

Summary of the Office Action

In the February 8, 2008 Office Action, Claims 18-20, 22-23, 33-44, 46-48, 50-59 and 61-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,527,312, issued to Ray (hereinafter "Ray"), in view of U.S. Patent No. 5,989,255, issued to Pepper et al. (hereinafter "Pepper"). In addition, Claims 21, 26, 45 and 60 stand objected to by the Examiner as allowable but dependent from a rejected base claim.

Summary of the Amendment

Upon entry of this amendment, Applicants will have amended Claims 18, 33-34, 37-41, 44, 52-56, 59, 67 and 69-71. Applicants will have cancelled Claims 1-17, 19-22, 28-32 and 42. Please note that in the amendments to the claims, deletions are indicated by strikethrough (e.g. ~~deletion~~) or double brackets (e.g. [[word]]) and additions to the claims are underlined (e.g. addition). Applicants respectfully submit that the present application is in condition for allowance. Claims 24-25 and 27 have previously been withdrawn. Accordingly, Claims 18, 23, 26, 33-41 and 43-72 are currently pending and under examination in the present application.

Traversal of Rejection under 35 U.S.C. § 103(a)

In the Office Action, independent Claim 18 and various of its dependent claims stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray in view of Pepper. While Applicants reserve the right to prosecute these claims as originally filed, Applicants have amended Claim 18 in order to expedite prosecution of this Application. Accordingly, Applicants respectfully request that the rejection of Claims 18, as well as the claims dependent there from be withdrawn and that these claims be indicated as allowable over the art of record.

Applicants respectfully submit that Applicants' present claimed invention is fundamentally distinct from the disclosure in Ray. For example, Applicants' method is accomplished on a distinct patient population from that of Ray. In addition, Applicants' bone anchor enters the bone at a different point than does Ray, and resides at a different angle of

inclination than that disclosed in Ray. Third, while Applicants apply compression along Applicants' longitudinal axis of implantation, Ray is concerned about minimizing lateral movement, transverse to the longitudinal axis of the Ray implant. As a consequence of these differences, Applicants respectfully submit that Ray neither discloses nor suggests Applicants' claimed invention.

Ray is directed to achieving spinal fusion in only that subset of patients in whom a laminectomy has been accomplished. Ray discloses that conventional translaminar screw fixation may not be adequate to stabilize successive vertebra in those patients having first received a laminectomy. *See, e.g.*, column 1 lines 37 through 41:

When a laminectomy is required, the spinous process and the underlying lamina are removed. When the spinous process is removed, translaminar screw fixation is not generally adequate to stabilize successive vertebra pending healing of the spinal fusion.

Thus, referring to Figures 1, 2 and 3 in Ray, a laminectomy has been performed. The spinous process and the underlying lamina on each side of the sagittal plane have been removed. See column 2 lines 30 through 34. The facet screw 20 is inserted "through the lamina 22" (column 2 line 37) and "angles laterally outwardly into the left base of the transverse process 24 of the inferior vertebra". Column 2 lines 39 through 41. A pair of screws are introduced with bilateral symmetry, such that "the screws 20 and 30 diverge in the anterior direction, and are also angled slightly in the inferior direction". Column 2 lines 47 through 49.

In other words, the conventional screw utilized by Ray enters the lamina in a patient following laminectomy, and extends into the transverse process.

In contrast, Applicants' bone anchor enters the native facet on a superior vertebral body and extends into the pedicle.

Claim 18 recites, in pertinent part, as follows:

advancing the bone anchor of the fixation device through a native facet of a first vertebra to position the bone anchor within a pedicle of a second vertebra . . .

Applicants respectfully submit that Ray's disclosure of extending from the lamina into the transverse process fails to disclose or suggest Applicants' claimed axial orientation of extending through the native facet and entering the pedicle.

Nor is there any reason why one would seek to apply axial compression along the axis of the screw disclosed in Ray. Ray's concern is with transverse motion of the screw, as a consequence of weakened bone due to the laminectomy. That is why Ray discloses the use of fixation bars 26 and 36, to minimize lateral movement of the screws 20 and 30.

Ray observed that following laminectomy, "the lamina is relatively weak, the trans laminar screws can toggle relative to the superior vertebra, causing breakage in the lamina around the screw and destabilization of the joint." Column 1 lines 43 through 46. As a consequence, Ray discloses providing a fixation bar 26 and 36 for each of the facet screws 20 and 30. The fixation bars form a hook that extends over and around the adjacent pedicle to secure the bar from movement in an inferior direction. Column 3 lines 3 through 6. This arrangement resists lateral "toggling" of the bone screw, as can be appreciated by reference to Figure 1 in Ray.

In contrast, Applicants' present claimed invention recites advancing the fixation device through a native facet in the absence of a laminectomy. As a consequence of Applicants' procedure, Applicants are less concerned about toggling in a transverse direction. Instead, Applicants desire to place the adjacent bones under compression along the axis of Applicants' fixation device. This is neither disclosed nor suggested in Ray.

Nor does Pepper suggest modifying Ray in a manner that would produce the claimed invention. Although Pepper does disclose an orthopedic device which is capable of applying axial compression, there is no reason of record why a person of skill in the art would combine the teachings of Pepper and Ray to produce Applicants' claimed invention.

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For example, nothing in Pepper would suggest changing the angular orientation of the screws disclosed in Ray, away from the lamina to transverse process axis as disclosed in Ray and instead toward the presently claimed native facet to pedicle axis of Applicants' present invention.

At most, the combination of the teachings of Pepper and Ray would likely produce a method as disclosed in Ray, in which the Pepper compression screw is introduced into the lamina of a laminectomy patient and extends into the transverse process as disclosed in Ray, and is provided with an anti-toggle bar. This fails to disclose or suggest Applicants' claimed invention.

In view of the foregoing, Applicants respectfully request that the rejection of Claim 18 be withdrawn. Dependent Claims 23, 26 through 27, 33 through 41 and 43 all depend ultimately from Claim 18, and are believed to be allowable for at least the reasons discussed above.

Independent Claim 44 similarly recites that the fixation device is advanced "through a facet of a first vertebra and into a pedicle of a second vertebra". Accordingly, Applicants respectfully submit that Claim 44 is allowable for at least the reasons discussed in connection with Claim 18. Dependent Claims 45 through 58 depend ultimately from independent Claim 44, and are believed to be allowable at least for that reason.

Independent Claim 59 recites, among other things, the method step of advancing the distal anchor of the fixation device "through a facet of a first vertebra and into a pedicle of a second vertebra". Applicants respectfully submit that this claim is therefore allowable at least for the reasons discussed in connection with Claim 18. Dependent Claims 60 through 72 all ultimately depend from Claim 59, and are believed to be in condition for allowance at least for the reasons discussed above.

Applicants respectfully submit that all pending claims in the present application are therefore in condition for allowance. In addition to the amendment discussed above, certain housekeeping amendments have been made to the claims such as to resolve potential antecedent basis issues, improve the readability of the claims and/or simplify the issues presented for examination.

Drawings

At the interview, a discrepancy in the Figure 20 was noted. Specifically, the Examiner had the version of Figure 20 that was submitted on April 19, 2007 when formal drawings were submitted. This version of Figure 20 included a fixation device that extended across the spinous

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process. This "additional" fixation device was not shown in the version of Figure 20 that was originally filed with this patent application. A fixation device that does extend across the spinous process is shown in Figure 19. This fixation device was inadvertently copied into Figure 20 when the drawings were formalized for the replacement drawings filed on April 19, 2007. The replacement Figure 20 submitted herewith corrects this informality by removing the additional fixation device. As noted above, this change is consistent with the original version of Figure 20. Accordingly, no new matter has been added.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/199,516	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	8/8/2005
11/444,103	LOCKING PLATE FOR BONE ANCHORS	5/31/2006
11/623,270	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005
11/623,290	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005

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Serial Number	Title	Filed
11/036,781	GUIDANCE SYSTEM FOR SPINAL STABILIZATION	1/14/2005
11/056,991	METHOD AND APPARATUS FOR SPINAL STABILIZATION	07/20/2005
11/296,881	METHOD AND APPARATUS FOR SPINAL STABILIZATION	12/08/2005
11/050,975	METHOD AND APPARATUS FOR SPINAL FUSION	2/4/2005
10/830,631	METHOD AND APPARATUS FOR BONE FIXATION WITH SECONDARY COMPRESSION	4/23/2004
12/134,886	METHOD AND APPARATUS FOR SPINAL STABILIZATION	6/06/2008

CONCLUSION

Applicants respectfully submit that the above rejections and objections have been overcome and that the present application is now in condition for allowance. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the Applicants' attorney in order to resolve such issue promptly.

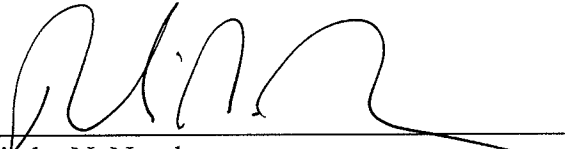
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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